

REMARKS

Claims 1-87 are pending. Claims 26-87 have been withdrawn by the Examiner. New claims 88-113 have been added. No other amendments have been made. Claims 1-25 and 88-113 are under consideration.

Claim 88 is similar to originally filed claim 1. Claim 88 differs from claim 1 in that claim 88 has the added language "the biological sample" in the claimed composition. Support for this added language can be found, e.g., in the specification at page 24, lines 5-18; page 30, lines 8-18; page 34, lines 1-7; and page 36, lines 17-22. New claim 89 depends from claim 88, and recites the language "wherein the biological sample is whole tissue." Support for claim 89 can be found throughout the specification, e.g., at page 14, lines 8-17; page 15, lines 20-22; page 16, lines 12-20; page 24, lines 5-18; page 30, lines 8-18; page 34, lines 1-7; and page 36, lines 17-22. Claims 90-113 are identical to claims 2-25, but ultimately depend from claim 88. Claims 88-113 add no new matter.

Rejection Under 35 U.S.C. § 102(b)

The Examiner rejects claims 1-3, 7-11, and 15 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Pat. No. 5,010,183 to Macfarlane ("Macfarlane I"). Office Action at pages 2 to 3, Item No. 3.

Applicant respectfully traverses the rejection. For a reference to anticipate the claimed invention under 35 U.S.C. § 102, the reference must describe the invention such that "each and every limitation is found either expressly or inherently" within it.

Transclean Corp. v. Bridgewood Services, Inc., 290 F.3d 1364, 1370, 62 USPQ2d

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1865, 1869 (Fed. Cir. 2002) (citations omitted); see Manual of Patent Examining Procedure § 2131 (8th ed. 2001) ("MPEP") ("to anticipate a claim, the reference must teach every element of the claim").

Claim 1 of the present application recites a composition for releasing nucleic acids from a biological sample that comprises at least one cationic surfactant, at least one protease, and a buffer. Claims 2-3, 7-11, and 15 all ultimately depend from claim 1.

The Examiner states that Macfarlane I "discloses a method for purifying DNA and RNA from a variety of sources ... employing a cationic detergent to complex with the nucleic acids." Office Action, page 2, section 3. Further, although the Examiner does not cite a particular part of Macfarlane I, she contends that Macfarlane I discloses the use of "hydrolytic enzymes, such as proteinase K." Office Action, page 3.

Macfarlane I does discuss the use of a cationic detergent. Further, Macfarlane I also discusses the possibility of using hydrolytic enzymes to disperse tissues before the release of nucleic acids. However, claim 1 recites a composition comprising at least one cationic surfactant, at least one protease, and a buffer. Nowhere does Macfarlane I discuss the use of a composition comprising both at least one cationic surfactant and at least one protease.

Further, the Examiner fails to establish or even assert that Macfarlane I discloses the use of a buffer in a composition for the release of nucleic acids. Macfarlane I discusses the use of a solvent. Macfarlane I, Col. 5, lines 39-51. Applicant asserts that a solvent is not necessarily a buffer. Macfarlane I also mentions the use of buffered solutions for resuspending nucleic acids after they have precipitated. Macfarlane I, Col.

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6, lines 37-39. However, Macfarlane I does not mention the use of a composition for releasing nucleic acid comprising a buffer.

For at least the reasons presented above, the Examiner has failed to establish that Macfarlane I would have anticipated claim 1. Claims 2, 3, 7-11, and 15 ultimately depend from claim 1, and for at least the reasons presented above, are not anticipated by Macfarlane I. Moreover, Applicant need not address the rest of the Examiner's contentions concerning Macfarlane I with respect to other limitations of certain dependent claims. By not addressing those contentions, Applicant in no way acquiesces to those contentions.

Reconsideration and withdrawal of the §102 rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejects claims 1-25 under 35 U.S.C. § 103(a) as allegedly being obvious over Macfarlane I in view of U.S. Pat. No. 5,728,822 to Macfarlane ("Macfarlane II"). Office Action, pages 4 to 6, Item No. 5.

The Examiner states that Macfarlane I discloses a method for "purifying DNA and RNA from a variety of sources ... employing a cationic detergent to complex with nucleic acids." Office Action, page 4, Item No. 5. The Examiner also alleges that Macfarlane II discloses a method "for isolating RNA from a biological sample ... involving the use of an aqueous, cationic surfactant solution comprising a quaternary amine." *Id.*, at page 5, lines 1-3.

As discussed above, claim 1 recites a composition for releasing nucleic acids from a biological sample comprising at least one cationic surfactant, at least one

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protease, and a buffer. All of claims 2-25 ultimately depend from claim 1, and thus include all of the limitations of claim 1. As discussed above, the Examiner fails to establish that Macfarlane I teaches a composition for releasing nucleic acids comprising at least one cationic surfactant, at least one protease, and a buffer. Moreover, the Examiner fails to assert, let alone establish that Macfarlane I would have suggested such a composition. Macfarlane II does not remedy the deficiencies of Macfarlane I.

Further, Macfarlane II does not teach and would not have suggested a composition for releasing nucleic acids comprising at least one cationic surfactant, at least one protease, and a buffer.

Thus, the Examiner has failed to establish that the combination of Macfarlane I and Macfarlane II would have rendered obvious any of the rejected claims. Moreover, applicant need not address the Examiner's contentions concerning the combination of Macfarlane I and Macfarlane II with respect to other limitations of certain dependent claims. By not addressing those contentions, Applicant in no way acquiesces to those contentions.

Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 1-25 in view of Macfarlane I and Macfarlane II.

Conclusion

Applicant respectfully asserts that the application is in condition for allowance. If the Examiner does not consider the application to be in condition for allowance, Applicant requests that the Examiner call the undersigned (650 849-6676) to arrange an interview prior to taking action.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: March 21, 2003

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